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PATENT COOPERATION TREATY

PCT Application
PCT/JP2003/008763

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

#7

Applicant's or agent's file reference PCT-TMP0004	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP2003/008763	International filing date (day/month/year) 10 July 2003 (10.07.2003)	Priority date (day/month/year) 12 July 2002 (12.07.2002)
International Patent Classification (IPC) or national classification and IPC A61K 35/78, 45/00, 9/20, 47/04, 47/38, 47/46, 47/48, A61P 43/00		
Applicant TSUMURA & CO.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 10 July 2003 (10.07.2003)	Date of completion of this report 28 November 2003 (28.11.2003)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP2003/008763

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-7	YES
	Claims		NO
Inventive step (IS)	Claims	1-7	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-7	YES
	Claims		NO

2. Citations and explanations

- Document 1: JP 56-152416 A (Tsumura Juntendo Co., Ltd.), 26 November 1981, (Family: none)
- Document 2: JP 61-33122 A (Daicel Chemical Ind., Ltd.), 17 February 1986, (Family: none)
- Document 3: JP 11-60504 A (Tsumura & Co.), 02 March 1999, (Family: none)
- Document 4: Chemical Abstracts, 10 August 1959, Vol. 53, No. 15, 14419h-i, 14420a, AN.1959:79551, DN.53:79551: W. R. WENSLEY et al., "Release of Medication from Compressed Formulations," Canadian Pharm. Journal, 1959, 92, pages 141-144
- Document 5: WO 00/37043 A1 (Dr. Regenold GmbH), 29 June 2000, page 13, example 2, & DE 19859231 A & AU 2283500 A & EP 1140013 A & JP 2002-532533 A
- Document 6: EP 1035196 A1 (Rohm and Haas Co.), 13 September 2000, page 2 paragraph [0003], & AU 1758500 A & CN 1266081 A & JP 2000-302933 A & US 6254892 B1

Documents 1-6 above are cited in the international search report.

Documents 2 and 3 disclose the feature of adding cellulose glycolic acid (document 2) or sodium hydrogen carbonate (document 3) to a capsule that contains an extract from a traditional Chinese medicine in order to improve the disintegration and elution properties thereof. In addition, documents 4 and 5 indicate capsules that comprise either one of these compounds. However, documents 1-6 do not disclose the feature of adding a mixture of the cellulose glycolic acid and the sodium hydrogen carbonate that are disclosed in documents 2 and 3 to a capsule that contains an extract from a traditional Chinese medicine in order to improve the disintegration and elution properties thereof, or the feature of significantly decreasing the disintegration period and increasing the elution rate of a capsule that contains an extract from a traditional Chinese medicine by further adding silicic anhydride to the abovementioned mixture, and these features are not considered to be obvious to a person skilled in the art.

Therefore, the inventions that are set forth in claims 1-7 are novel and involve an inventive step.

The inventions that are set forth in claims 1-7 exhibit industrial applicability.